SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Versiguard Rabies suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (1 ml) contains:

Active substance:

Inactivated rabies virus, strain SAD Vnukovo-32 ≥ 5 IU*

* IU – international units.

Adjuvant:

Aluminium hydroxide 2.0 mg.

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Thiomersal	0.1 mg
Water for injections	

The visual appearance is as follows: slightly pink suspension, which might contain fine sediments.

3. CLINICAL INFORMATION

3.1 Target species

Dogs, cats, cattle, pigs, sheep, goats, horses and ferrets.

3.2 Indications for use for each target species

For the active immunisation of dogs, cats, cattle, pigs, sheep, goats, horses and ferrets (12 weeks of age and older) to prevent infection and mortality caused by rabies virus.

Onset of immunity:

14–21 days after primary vaccination.

Duration of immunity:

Dogs: three years following the primary vaccination course.

Cats, cattle, pigs, sheep, goats, horses and ferrets: one year after primary vaccination, and two years after booster vaccinations.

3.3 Contraindications

Do not use in animals that are showing signs of rabies or that are suspected of being infected with rabies virus.
Do not use in cases of hypersensitivity to the adjuvant or to any of the excipients.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

In the case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site swelling[1] Hypersensitivity reaction[2]

[1]Transient, following subcutaneous administration which may reach up to 10 mm in diameter and in rare cases be associated with mild discomfort. Usually resolves within 10 days.
[2]Appropriate treatment should be administered without delay.

Cats, cattle, pigs, sheep, goats, horses and ferrets:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site pain[1], Injection site swelling[2] Hypersensitivity reaction[3]

[1]Mild and associated with injection site swelling.
[2]Transient.

- following intramuscular administration may reach up to 2 cm in diameter and usually resolves within 7 days.
- following subcutaneous administration may reach up to 10 mm in diameter and usually resolves within 10 days. In rare cases may be associated with mild discomfort.

[3]Appropriate treatment should be administered without delay.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder <or its local representative> or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Can be used during pregnancy.

The vaccine has not been extensively tested in lactating animals. However, the limited data that are available indicate that administration of the vaccine to lactating animals will not be associated with an increased incidence of adverse reactions.

3.8 Interaction with other medicinal products and other forms of interaction

Dogs

Safety and efficacy data are available which demonstrate that this vaccine can be administered subcutaneously in dogs on the same day as vaccines from the Vanguard range (Vanguard 7, Vanguard Plus 7, Vanguard Plus 5, Vanguard Plus 5L, Vanguard Pup, Vanguard Puppy, Vanguard CPV, Vanguard CPV +L, Vanguard DA2Pi, Vanguard DA2Pi+L, Vanguard Lepto ci where approved), either mixed or at different sites. The duration of immunity for the Vanguard range when used with Versiguard Rabies has not been established.

After concurrent or mixed administration of Versiguard Rabies and Vanguard canine range, vaccinated dogs may have a transient swelling (up to 6 cm) at the injection site and a transient swelling of the sub-mandibular and/or pre-scapular lymph nodes at the injection site 4 hours after vaccination. These signs resolve within 24 hours.

Safety and efficacy data are available which demonstrate that this vaccine can also be used as solvent for the live vaccines of the Versican Plus range (Versican Plus DHPPi, DHP, DP, P and Pi) and administered subcutaneously in dogs. After mixed administration with the Versican Plus range vaccinated dogs may commonly have a transient swelling (up to 5 cm) at the injection site. The swelling can occasionally be painful, warm or reddened. Any such swelling will either have spontaneously resolved or be greatly diminished by 14 days after vaccination. In rare cases gastrointestinal signs such as diarrhoea and vomiting or anorexia and decreased activity are possible.

Use as solvent for the Versican Plus range:
The contents of a single vial of Versican Plus vaccine should be reconstituted with the contents of a vial containing 1 dose of Versiguard Rabies (instead of the solvent). Once mixed, the contents of the vial should appear a pink/red or yellowish colour with light opalescence. The mixed vaccines should be injected immediately via the subcutaneous route.

Co-administration with Vanguard canine range:
To mix both products, Vanguard vaccines should be reconstituted according to their SPCs. The reconstituted vial will be well shaken and then mixed with 1 ml of Versiguard Rabies either in the Versiguard Rabies vial or the syringe. Versiguard Rabies will be well shaken before use. The mixed vaccines will be gently shaken and then administered immediately by subcutaneous injection.

Other target species
No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

3.9 Administration routes and dosage

Dogs: administer by subcutaneous injection.
All other species: administer by subcutaneous or intramuscular injection.

Shake the vial before use.

Dosage:
A single dose of 1 ml is sufficient irrespective of age, weight or animal species.

Primary vaccination scheme:
Animals of all target species can be vaccinated from 12 weeks of age.
Primary vaccination is with a single dose of vaccine.

Re-vaccination scheme:

Dogs: a single dose of Versiguard Rabies should be given every 3 years. Antibody titres drop over the course of the 3-year duration of immunity, although dogs are protected when challenged. In case of travelling to risk areas or outside the EU, veterinary surgeons may wish to give additional rabies vaccinations to ensure that the vaccinated dogs have an antibody titre ≥ 0.5 IU/ml, which is generally regarded

as sufficiently protective and that they meet the travel test requirements (antibody titres ≥ 0.5 IU/ml).

Cats, cattle, pigs, sheep, goats, horses and ferrets: animals should be revaccinated with one dose of vaccine 1 year after primary vaccination.

After the first booster vaccination (administered 1 year after primary vaccination), animals should be revaccinated every 2 years with one dose of vaccine.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Local reactions after subcutaneous vaccination with an overdose tended to larger (up to 12 mm in diameter) than after a standard dose.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

National rabies control legislation may require different vaccination programmes to that recommended in section 3.9 (e. g., more frequent vaccination) or may restrict rabies vaccination to particular target species.

<Official control authority batch release is required for this product.>

3.12 Withdrawal periods

Dogs, cats, ferrets: Not applicable.
Cattle, pigs, sheep, goats, horses: Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI07AA02

The vaccine stimulates active immunity in the target species against rabies.

As required by the European Pharmacopoeia, efficacy was demonstrated by challenge in dogs and cats, and by serology in the other target species. One year after primary vaccination, 100% of dogs and cats vaccinated via either the subcutaneous or intramuscular routes were protected against challenge. Two years after booster vaccination, protection rates against challenge were 92% of cats vaccinated via either the subcutaneous or intramuscular routes. Three years after primary vaccination, 96% of dogs vaccinated by subcutaneous route were protected against challenge. Protection rates against challenge in dogs and cats, and serology results for the other target species, comply with the efficacy criteria of the European Pharmacopoeia for inactivated rabies vaccine at both the one-year, two-year and three-year assessments.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product except those mentioned in section 3.8 above

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 10 hours.

5.3 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).
Do not freeze.
Protect from light.

5.4 Nature and composition of immediate packaging

The vaccine is supplied in type I (1 ml or 10 ml) glass vials complying with Ph. Eur., sealed with a bromobutyl rubber stopper and aluminium cap.

Cardboard box of 1 vial of 1 ml.
Plastic box of 10 vials of 1 ml or 10 ml.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited

7. MARKETING AUTHORISATION NUMBER

Vm 42058/3013

8. DATE OF FIRST AUTHORISATION

03 December 2015

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

November 2023

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary

Approved 06 November 2023